Vaccine Safety Meeting
Wednesday, May 31, 2017
2:00 – 4:00 PM
Medical Board Room
NIH Clinical Center, 4-2551

PARTICIPANTS:

World Mercury Project:
Robert F. Kennedy Jr.
Del Matthew Bigtree
George Wayne Lucier
John Forrest Maready
Lyndell H. Redwood
Aaron Siri

US Government:
Reed Cordish, Assistant to the President for Intragovernmental and Technology Initiatives
Mary-Sumpter Lapinksi, Counselor to the Secretary of Health and Human Services
Francis Collins, Director NIH
Lawrence Tabak, Principal Deputy Director, NIH
Diana Bianchi, Director, Eunice Kennedy Shriver Institute of Child Health and Human Development (NICHD)
Linda Birnbaum, Director, National Institute of Environmental Health Sciences (NIEHS)
Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID)
Joshua Gordon, Director, National Institute of Mental Health
Carrie Wolinetz, Associate Director for Science Policy and Acting Chief of Staff to the NIH Director

AGENDA:

Introductions, *all*

Welcome and mission of NIH, *Francis Collins*

Presentation on vaccine safety, *Robert F. Kennedy Jr.*

Discussion

Discussion Points:

- Current understanding of the health effects of thimerosal/mercury exposure
- Vaccine safety and risks associated with reduced vaccination rates
- Causes of autism, including genetic and environmental influences
- Possible future research into screening and early intervention for autism spectrum disorders

Francis S. Collins, M.D., Ph.D., Director of NIH

Francis S. Collins, M.D., Ph.D. was appointed the 16th Director of the National Institutes of Health (NIH) by President Barack Obama and was sworn in on August 17, 2009. In this role, he oversees the work of the largest supporter of biomedical research in the world, spanning the spectrum from basic to clinical research.

Dr. Collins is a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the international Human Genome Project, which culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. He served as director of the National Human Genome Research Institute at NIH from 1993-2008.

Before coming to NIH, Dr. Collins was a Howard Hughes Medical Institute investigator at the University of Michigan. He is an elected member of the National Academy of Medicine and the National Academy of Sciences, was awarded the Presidential Medal of Freedom in November 2007, and received the National Medal of Science in 2009.

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director of NIH

Dr. Tabak is the Principal Deputy Director of the National Institutes of Health (NIH) and the Deputy Ethics Counselor of the Agency. He previously served as the Acting Principal Deputy Director of NIH (2009), and prior to that as Director of the National Institute of Dental and Craniofacial Research from 2000-10.

Dr. Tabak has provided leadership for numerous trans-NIH activities, including the NIH Roadmap effort to support team science, known as the NIH Common Fund; the NIH Director's initiative to enhance peer review; NIH's American Recovery and Reinvestment Act implementation; the NIH initiative to enhance rigor and reproducibility in research; and the NIH-Wide Strategic Plan. He co-chaired working groups of the Advisory Committee to the Director of NIH on the Diversity of the Biomedical Research Workforce and the Long-Term Intramural Research Program Planning. Dr. Tabak also served as the interim program director of the trans-NIH Environmental influences on Child Health Outcomes (ECHO) program.

Prior to joining NIH, Dr. Tabak was the Senior Associate Dean for Research and Professor of Dentistry and Biochemistry & Biophysics in the School of Medicine and Dentistry at the University of Rochester in New York. A former NIH MERIT recipient, Dr. Tabak's major research focus has been on the structure, biosynthesis and function of glycoproteins. He continues work in this area, maintaining an active research laboratory within the NIH intramural program in addition to his administrative duties. He is an elected member the National Academy of Medicine (formerly, the IOM).

Diana W. Bianchi, M.D., Director of NIMH

Diana W. Bianchi is the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. In this role, she oversees the Institute's research on pediatric health and development, maternal health, reproductive health, intellectual and developmental disabilities, and rehabilitation medicine, among other areas. These efforts include managing a staff of approximately 1,400 people and an annual budget of approximately $1.3 billion. Dr. Bianchi serves as an ambassador and spokesperson for NICHD.

Dr. Bianchi received her B.A. *magna cum laude* from the University of Pennsylvania and her M.D. from Stanford University School of Medicine. She completed her residency training in Pediatrics at the Children's Hospital, Boston and her postdoctoral fellowship training in Medical Genetics and Neonatal-Perinatal Medicine, both at Harvard. She is board-certified in all three specialties and is a practicing medical geneticist with special expertise in reproductive genetics. Dr. Bianchi's translational research focuses on two broad themes: prenatal genomics with the goal of advancing noninvasive prenatal DNA screening and diagnosis, and investigating the fetal transcriptome to develop new therapies for genetic disorders that can be given prenatally.

Dr. Bianchi has published over 290 peer-reviewed articles, and she is one of four authors of Fetology: Diagnosis and Management of the Fetal Patient. This book won the Association of American Publishers award for best textbook in clinical medicine in 2000. The second edition was published in April 2010 and is in its third printing. It has been translated into Japanese, Mandarin, and Spanish.

Dr. Bianchi is recognized widely for her leadership roles. She spent 23 years at Tufts Medical Center, where she was the founding Executive Director of the Mother Infant Research Institute, as well as the Natalie V. Zucker Professor of Pediatrics, Obstetrics and Gynecology at Tufts University School of Medicine. Dr. Bianchi also was the Vice Chair for Pediatric Research at the Floating Hospital for Children, Boston. From 2011 through 2015, she served on the National Advisory Council of NICHD. She is currently Editor-in-Chief of the international journal Prenatal Diagnosis and is a Past President of the International Society for Prenatal Diagnosis and the Perinatal Research Society. She is a former member of the Board of Directors of the American Society for Human Genetics and a former council member of both the Society for Pediatric Research and the American Pediatric Society. She was elected to membership in the National Academy of Medicine (formerly the Institute of Medicine) in 2013.

Dr. Bianchi has received two major lifetime achievement awards. The Landmark Award, from the American Academy of Pediatrics, was given in 2015 in recognition of her research and contributions to genetics and newborn care. The Maureen Andrew Award for Mentoring, given in 2016 by the Society for Pediatric Research, recognized her commitment to mentoring the next generation of clinician-scientists.

Linda S. Birnbaum, Ph.D., Director of NIEHS

Linda S. Birnbaum, Ph.D., is director of the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health, and the National Toxicology Program (NTP). As NIEHS and NTP director, Birnbaum oversees a budget of more than $740 million that funds biomedical research to discover how the environment influences human health and disease. The institute also supports training, education, technology transfer, and community outreach. NIEHS currently funds more than 1,000 research grants.

A board certified toxicologist, Birnbaum has served as a federal scientist for nearly 35 years. Prior to her appointment as NIEHS and NTP director in 2009, she spent 19 years at the U.S. Environmental Protection Agency (EPA), where she directed the largest division focusing on environmental health research. Birnbaum started her federal career with 10 years at NIEHS, first as a senior staff fellow in the National Toxicology Program, then as a principal investigator and research microbiologist, and finally as a group leader for the institute's Chemical Disposition Group.

Birnbaum has received many awards and recognitions. In October 2010, she was elected to the Institute of Medicine of the National Academies, one of the highest honors in the fields of medicine and health. She was also elected to the Collegium Ramazzini, and received an honorary Doctor of Science from the University of Rochester, and a Distinguished Alumna Award from the University of Illinois.

Other awards include two NIH Director's Award, a Women in Toxicology Elsevier Mentoring Award, Society of Toxicology Public Communications Award, EPA Health Science Achievement Award and Diversity Leadership Award, 2012 National Center for Women Health Policy Hero Award, Breast Cancer Fund Heroes Award, 2013 American Public Health Association Homer N. Calver Award, 2013 Children's Environmental Health Network Child Health Advocate Award, 2014 Mailman School of Public Health Granville H. Sewell Distinguished Lecturer award, an honorary doctorate from Ben-Gurion University in Israel, 2014 Surgeon General's Medallion, and 14 Scientific and Technological Achievement Awards, which reflect the recommendations of EPA's external Science Advisory Board, for specific publications.

Birnbaum is also an active member of the scientific community. She was vice president of the International Union of Toxicology, the umbrella organization for toxicology societies in more than 50 countries; former president of the Society of Toxicology, the largest professional organization of toxicologists in the world; former chair of the Division of Toxicology at the American Society for Pharmacology and Experimental Therapeutics; and former vice president of the American Aging Association.

She is the author of more than 700 peer-reviewed publications, book chapters, and reports. Birnbaum's research focuses on the pharmacokinetic behavior of environmental chemicals, mechanisms of action of toxicants including endocrine disruption, and linking of real-world exposures to health effects. She is an adjunct professor in the Gillings School of Global Public

Health, the Curriculum in Toxicology, and the Department of Environmental Sciences and Engineering at the University of North Carolina at Chapel Hill, as well as in the Integrated Toxicology and Environmental Health Program at Duke University.

A native of New Jersey, Birnbaum received her M.S. and Ph.D. in microbiology from the University of Illinois at Urbana-Champaign.

Anthony S. Fauci, M.D., Director of NIAID

Dr. Fauci was appointed Director of NIAID in 1984. He oversees an extensive research portfolio of basic and applied research to prevent, diagnose, and treat established infectious diseases such as HIV/AIDS, respiratory infections, diarrheal diseases, tuberculosis and malaria as well as emerging diseases such as Ebola and Zika. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies. The NIAID budget for fiscal year 2017 is approximately $4.7 billion.

Dr. Fauci has advised five Presidents and the U.S. Department of Health and Human Services on HIV/AIDS and many other domestic and global health issues. He was one of the principal architects of the President's Emergency Plan for AIDS Relief (PEPFAR), a program that has saved millions of lives throughout the developing world.

Dr. Fauci also is the long-time chief of the Laboratory of Immunoregulation. He has made many contributions to basic and clinical research on the pathogenesis and treatment of immune-mediated and infectious diseases. He helped pioneer the field of human immunoregulation by making important basic scientific observations that underpin the current understanding of the regulation of the human immune response. In addition, Dr. Fauci is widely recognized for delineating the precise ways that immunosuppressive agents modulate the human immune response. He developed effective therapies for formerly fatal inflammatory and immune-mediated diseases such as polyarteritis nodosa, granulomatosis with polyangiitis (formerly Wegener's granulomatosis), and lymphomatoid granulomatosis. A 1985 Stanford University Arthritis Center Survey of the American Rheumatism Association membership ranked Dr. Fauci's work on the treatment of polyarteritis nodosa and granulomatosis with polyangiitis among the most important advances in patient management in rheumatology over the previous 20 years.

Dr. Fauci has made seminal contributions to the understanding of how HIV destroys the body's defenses leading to its susceptibility to deadly infections. Further, he has been instrumental in developing treatments that enable people with HIV to live long and active lives. He continues to devote much of his research on the immunopathogenic mechanisms of HIV infection and the scope of the body's immune responses to HIV.

In 2003, an Institute for Scientific Information study indicated that in the 20-year period from 1983 to 2002, Dr. Fauci was the 13th most-cited scientist among the 2.5 to 3 million authors in all disciplines throughout the world who published articles in scientific journals during that time frame. In a 2016 analysis of Google Scholar citations, he ranked as the 18th most highly cited researcher of all time.

Dr. Fauci has delivered major lectures all over the world and is the recipient of numerous prestigious awards, including the Presidential Medal of Freedom (the highest honor given to a civilian by the President of the United States), the National Medal of Science, the George M. Kober Medal of the Association of American Physicians, the Mary Woodard Lasker Award for Public Service, the Albany Medical Center Prize in Medicine and Biomedical Research, the Robert Koch Gold Medal, the Prince Mahidol Award, and the Canada Gairdner Global Health Award. He also has received 43 honorary doctoral degrees from universities in the United States and abroad.

Dr. Fauci is a member of the National Academy of Sciences, the American Academy of Arts and Sciences, the Institute of Medicine, and the American Philosophical Society, as well as other professional societies including the American College of Physicians, The American Society for Clinical Investigation, the Association of American Physicians, the Infectious Diseases Society of America, The American Association of Immunologists, and the American Academy of Allergy, Asthma & Immunology. He serves on the editorial boards of many scientific journals; as an editor of *Harrison's Principles of Internal Medicine*; and as author, coauthor, or editor of more than 1,300 scientific publications, including several textbooks.

Joshua A. Gordon, M.D., Ph.D., Director of NIMH

Joshua A. Gordon, M.D., Ph.D. is the Director of the National Institute of Mental Health (NIMH). NIMH is the lead federal agency for research on mental disorders.

Dr. Gordon pursued a combined M.D.-Ph.D. degree at the University of California, San Francisco (UCSF). Medical school coursework in psychiatry and neuroscience convinced him that the greatest need, and greatest promise, for biomedical science was in these areas. During his Ph.D. thesis with Dr. Michael Stryker, Dr. Gordon pioneered the methods necessary to study brain plasticity in the mouse visual system.

Upon completion of the dual degree program at UCSF, Dr. Gordon went to Columbia University for his psychiatry residency and research fellowship because of the breadth and depth of the research opportunities there. Working with Dr. Rene Hen, Dr. Gordon and colleagues studied the role of the hippocampus, a brain structure known to be important for memory and emotional processes associated with anxiety and depression. He joined the Columbia faculty in 2004 as an assistant professor in the Department of Psychiatry.

Dr. Gordon’s research focuses on the analysis of neural activity in mice carrying mutations of relevance to psychiatric disease. His lab studied genetic models of these diseases from an integrative neuroscience perspective, focused on understanding how a given disease mutation leads to a behavioral phenotype across multiple levels of analysis. To this end, he employs a range of systems neuroscience techniques, including in vivo imaging, anesthetized and awake behavioral recordings, and optogenetics, which is the use of light to control neural activity. His research has direct relevance to schizophrenia, anxiety disorders, and depression.

In addition to his research, Dr. Gordon was an associate director of the Columbia University/New York State Psychiatric Institute Adult Psychiatry Residency Program, where he directed the neuroscience curriculum and administered research training programs for residents. Dr. Gordon also maintained a general psychiatric practice, caring for patients who suffer from the illnesses he studied in his lab at Columbia.

Dr. Gordon's work has been recognized by several prestigious awards, including the Brain and Behavior Research Foundation – NARSAD Young Investigator Award, the Rising Star Award from the International Mental Health Research Organization, the A.E. Bennett Research Award from the Society of Biological Psychiatry, and the Daniel H. Efron Research Award from the American College of Neuropsychopharmacology.

Carrie D. Wolinetz, Ph.D., Acting Chief-of-Staff and Associate Director for Science Policy, NIH

Carrie D. Wolinetz, Ph.D. is Acting Chief-of Staff to National Institutes of Health (NIH) Director Francis Collins, as well as serving as Associate Director for Science Policy and Director of the Office of Science Policy (OSP) at the NIH. As leader of OSP, she advises the NIH Director on science policy matters of significance to the agency, the research community, and the public, on a wide range of issues including human subjects protections, biosecurity, biosafety, genomic data sharing, regenerative medicine, the organization and management of NIH, and the outputs and values of NIH-funded research.

Prior to joining NIH, Dr. Wolinetz worked on biomedical research policy issues as the Deputy Director for Federal Affairs at the Association of American Universities (AAU) and the Director of Scientific Affairs and Public Relations at the Federation of American Societies for Experimental Biology (FASEB). She also served as the President of United for Medical Research, a leading NIH advocacy coalition. Outside of NIH, Dr. Wolinetz teaches as an Adjunct Assistant Professor at Georgetown University in the School of Foreign Service's program on Science, Technology & International Affairs.

She has a BS in animal science from Cornell University, and she received her PhD in animal science from The Pennsylvania State University, where her area of research was reproductive physiology.